Risiken erkennen – Gesundheit schützen

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Ihre Zeichen und Nachrichten vom	Gesch.-Z.: Bitte bei Antwort angeben	Tel.-Durchwahl/Fax	Datum	Org.-Einheit/Ansprechpartner
	92-5147-00-6281390	-2273/-2275 -2958	5 July 2011	Unit 92 - ZEBET Dr. Manfred Liebsch

BoNT-EWG COMMENT on Federal Register Notice Vol. 76 (No. 99) - May 23, 2011

Dear Dr. Casey

Please find enclosed a consolidated comment of the international BoNT Expert Working Group (BoNT EWG), which is co-chaired by the German Federal Institute for Risk Assessment (BfR, ZEBET) and the Federal Institute for Drugs and Medical Devices (BfArM),

on Federal Register Notice Vol. 76 (No.99) issued 23 May 2011

regarding comments and data on three *in vitro* test nominations proposed for detecting and quantifying botulinum neurotoxin (BoNT).

The BoNT EWG comprises experts from responsible European competent authorities, European 3R- and validation institutions, manufacturers and selected scientists, as well as observing non-European colleagues from the United States relevant to this work. The Federal Register Notice mentioned above was discussed by the BoNT EWG and the comment drafted and consolidated during the 4th meeting on June 16-17, 2011.

This consolidated comment is sent on behalf of the 20 members attending the 4th BoNT EWG Meeting.

Kind regards
Sincerely

(signature redacted)

Dr. Manfred Liebsch

ENCLOSURE

Consolidated Comment of the Botulinum Neurotoxin Testing Expert Working (BoNT EWG)

on:

„Nomination of *In vitro* Test Methods for the Detection and Quantification of Botulinum Neurotoxin and Detection of Non-Endotoxin Pyrogens; Data Request for Substances Evaluated by These Test Methods"

(US Federal Register Vol. 76/ No. 99 / Monday, May 23, 2011 / Notices).

The Expert Working Group (BoNT EWG) at the Federal Institute for Risk Assessment (for details see http://www.bfr.bund.de/en/botulinum_neurotoxin_potency_testing-70890.html) respectfully conveys the following comments pertaining to the document "Nomination of *In vitro* Test Methods for the Detection and Quantification of BoNT".

The BoNT EWG highly appreciates the NICEATM and ICCVAM activities to support the validation and implementation of alternative methods in BoNT potency testing. However, the BoNT EWG would recommend that during the evaluation there is a clear separation between the issues concerning food hygiene, diagnostic needs and potency testing of medicinal products. Alternative assays used in testing medicinal products need to be validated and cross validated with the LD_{50} method separately for the individual medicinal products.

With respect to the methods currently under consideration, we would like to underline that:

- To our knowledge, the BoCell™ assay is currently not validated for use in testing medicinal products but it could be considered for use provided the comparability with the LD_{50} is demonstrated

- The BoTest™ is an endopeptidase assay among others available that may be suitable for specific testing purposes during the production process of BoNT medicinal products with appropriate cross validation data

Berlin, 17 June 2011
Members of the BoNT EWG